



**UNITED STATES DEPARTMENT OF COMMERCE
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#125

Hollis G. Schoepke
Senior Vice President of R &D
Anaquest, Inc.
110 Allen Road
P.O. Box 804
Liberty Corner, NJ 07938

Re: Patent Term Extension
Application for
U.S. Patent No. 4,762,856

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,762,856 issued August 9, 1988, which claims the human drug product Suprane, is eligible for patent term extension under 35 USC § 156. The period of extension has been determined to be 405 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of February 9, 1993. Under 35 USC § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 (\text{Testing Phase}) + \text{Approval Phase} \\ &= 1/2 (771) + 598 \\ &= 984 \text{ days}\end{aligned}$$

Since the regulatory review period began after the patent issue date, the entire period has been considered. No determination of a lack of due diligence was made.

The 14 year exception of 35 USC § 156(c)(3) operates to limit the term of extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (September 18, 1992) when added to the period of extension calculated above (984 days) cannot exceed fourteen years. The period of extension is thus limited to September 18, 2006, by operation of 35 USC § 156(c)(3). Since the patent term of seventeen years (35 USC § 154) would expire on August 9, 2005, the period of extension is the number of days to extend the term of the patent from its expiration date to and including September 18, 2006, or 405 days.

The limitations of 35 USC § 156(g)(6) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,762,856 a certificate of extension, under seal, for a period of 405 days.

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No.:	4,762,856
Granted:	August 9, 1988
Applicant:	Ross C. Terrell
Owner of Record:	Anaquest, Inc.
Title:	ANESTHETIC COMPOSITION AND METHOD OF USING THE SAME
Classification:	514/722
Product Trade Name:	Suprane
Term Extended:	405 days

C. E. Van Horn

Charles E. Van Horn
Patent Policy & Projects Administrator
Office of the Assistant Commissioner for Patents

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: Suprane

FDA Docket No.: 92E - 0471